REMARKS

Election/Restriction

The examiner has required an election of species and such an election has been made. Applicant has withdrawn the dependent claims 2, 4, 6, 10, 12, 13, 27, 29, 33, 35, 36, and 46-52 and added new claims that are directed to the species: (A) B-vitamins; (B) ALA; (C) methyl donors; (D) huperzine A; (E) pyridoxine; and (F) vinpocetine. New claims 52-64 read on these species and are thereby allowable. It is, believed that the amended generic claims 1 and 24 are allowable, and thus all claims should be allowable. That is, though dependent claims 2-23 and 25-52 have been withdrawn, it is respectfully requested that after allowance of a generic claim, all claims dependent on the generic claims be considered and allowed.

Specification

In the Office Action dated February 7, 2003, the Examiner objected to the disclosure because it contains an embedded hyperlink and/or other form of browser-executable code on page 15, lines 17-18. Applicant has deleted the objectionable embedded hyperlink and has correctly cited the prior art reference. See MPEP § 707.05(e).

Claim Rejections – 35 USC § 112

In the Office Action dated February 7, 2003, the Examiner rejected claims 1, 2, 4, 6, 10, 12, 13, 24, 27, 29, 33, 35, 36, and 46-52 under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is respectfully traversed.

The Examiner in part bases his rejection on the fact that the active agents are disclosed by their function, not their chemical names. The Examiner provides no basis in either the MPEP or the law for such a rejection. In fact, in the case cited by the Examiner, *In re Wands*, 858 F.2d 731, 737, 8USPQ 2d, 1400, 1404 (Fed.Cir. 1998), a composition is described functionally. See *Wands Supra*, p. 1402, column 2. Further, the enclosed references show that each of the functions claimed are recognized and understood by those skilled in the art. Further, the written description discusses each

function in a manner that is understood by those skilled in the art and give profuse examples of compounds that perform such functions.

Claims 24, 27, 29, 33, 35, 36, and 46 – 52 were rejected under 35 U.S.C. 112, first paragraph on the basis that they allegedly contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to make or use the invention. The Examiner cites In re Wands, Supra, p. 1404 in support of this contention. However, *Wands* actually held oppositely to the position of the Examiner. Wands held that the claims in question were supported in an enabling fashion. See, *Wands, Supra*, p. 1407 under *IV Conclusions*. With respect to each of the factors mentioned by the examiner, we note the following.

The breath of the claims – The Nature of the invention

The present claims are much narrower then the claims in Wands since a combination of six agents is claimed. Further, as shown by the specification and the references enclosed, those skilled in the art understand each of the functions claimed.

The state of the prior art

References enclose show that each of the functions are well-known in the prior art, though a composition of the combination is not known.

The level of one of ordinary skill

As indicated by the examiner, the level of skill is very high. Thus, those of ordinary skill would understand fully the functions claimed and understand what is intended to be covered by the claims.

The level of predictability in the art

The examiner appears to believe that a requirement of patentability is that the claimed combination must show efficacy in treating all neurological disorders. There is not basis for this in the MPEP or the case law. The specification specifically discusses at least six disorders that the claimed combination is effective in treating. That is well-recognized in the law as an adequate basis for the claim.

The amount of direction provided by the inventor

Much less experimentation is required than specification required in Wands since many actual examples of the agents are given including the ranges of the amounts for about fifty such agents. Using the specification, one skilled in the art can

make more than a hundred example of the claimed invention. This is far more than was required in *Wands*.

The existence of working xamples

Working examples are given for each of the agents and for preferred combinations of agents.

The quantity of experimentation needed

Since absolutely no experimentation is needed to make hundreds of compositions of the claimed combination, much less experimentation is needed than was required in *Wands*.

Claims 1, 2, 4, 6, 10, 12, 13, 24, 27, 29, 33, 35, 36 and 46 – 52 were rejected under 35 U.S.C. 112, second paragraph on the basis of the terms such as "normalizing", "impaired", and "deteriorating". This rejection is respectfully traversed.

Claims 1 and 24 have been amended to claim a composition for "treating" impaired neurological function or deteriorating neurological function. The title of the patent application and the Summary paragraph on page 15, lines 23-24 have also been amended to reflect the change. It is believed that this amendment overcomes the rejection. Further, this and the above rejections are traversed for the following reasons.

Applicant does not intend to claim a composition for treating and curing any and all diseases relating to the nervous system and neurological disorders. Rather, due to increased understanding of the integrated nature of neuronal pathways of disease, the utility of analyzing all individual pathologic mechanisms at each potentially therapeutic site with the goal of developing a therapy that addresses the entire network of abnormalities involved clearly represents a quantum advance. It is by this analytic process that a truly unique and comprehensive therapeutic paradigm is provided in the present invention. (Page 29, lines 1-6). The claimed invention produces beneficial effects at many sites in various dysfunctional pathways. The present invention not only improves symptomalogy but actually functions at various sites to produce metabolic and physiologic changes which alter, modulate and improve or reverse the basic abnormalities responsible for the development of various neurological diseases. (Page 17, lines 3-5). The invention prevents, lessens, or reverses the attendant

neurological symptomalogy and, at the same time, ameliorates their causative mechanisms. (Page 17, lines 14-16).

Examiner also rejected the written description. Examiner's written description rejection claims that subject matter was not described in such a way as to reasonably convey to one skilled in the relevant art the ability to make and use the invention. Specifically included were the facts that the active agents are described by their function rather than their chemical structure; the invention is described by what it does rather than what it is; an inherent inability to distinguish the intended compound from other molecules that can perform the same function; and the need for undue experimentation.

The written description, including the Background of the Invention and the prior art disclosed in the supplemental IDS submitted herewith, provides the information necessary for one skilled in the art to which the present invention pertains, or with which it is most nearly connected, to make and/or use the invention as claimed in the appended claims. As stated in the title, the invention is directed at neurological function-specifically impaired or deteriorating neurological function. Several of the cited examples of prior patents also refer to "nervous system deterioration", "nervous symptoms", and "enhancing....performance". These all involve function. This invention is directed at improving function and is thus claims the invention by the function of the active ingredients since one skilled in the art understands that there are multiple agents that may be used to improve a particular function. As outlined in the Background section, functional neurological deterioration or dysfunction involves the development of concurrent aberrations in a network of complex mechanistic pathways of disease causation. These etiopathophysiologic pathways contribute to neurological deterioration and/or dysfunction and are amenable to therapeutic intervention. Simply stated, pathway dysfunction produces neurological dysfunction.

What is known from prior art is that categories of agents exist such that all agents included in a particular category share similar functional actions upon specific metabolic pathways. References from the literature supporting this assertion are included in Supplemental IDS submitted herewith. Although they share certain functional attributes, these agents are not identical and therefore manifest different overall metabolic profiles. These are also described in the references in the

Supplemental IDS. What is unique about this invention is the insight provided by a holistic approach involving the simultaneous utility of (numerous) agents from each of several different functional categories. The combination of this approach coupled with prior knowledge in the field regarding specific disease processes as well as the multiple functional attributes of each of the active agents allows one skilled in the art to choose each specific agent (and amount) and combinations of agents most beneficial for each condition.

Specific examples are provided throughout the Background section including listings of beneficial effects of administration of Huperzine A upon levels of dopamine, nor-epinephrine and acetylcholine, similar effects of Vinpocetine upon nor-epinephrine, phosphatidylserine modulation of dopamine, nor-epinephrine and acetylcholine, etc. Knowledge of the precise neurological impairment and the associated neurotransmitter pathology allows one skilled in the art to choose specific functional agents, precise amounts and combinations of such agents so as to ameliorate the abnormality involving the functional pathway of neurotransmission. This beneficially impacts the observed symptomatology. Similar observations apply for each functional category of agents.

The central feature of this invention involves functional impairments and beneficial functional actions of categories of agents upon these impairments. Choices of salient categories are made based upon prior medical art to maximize the beneficial functional impact. Choices of specific agents (and amounts) within a particular category are also driven by knowledge available to one skilled in the art as depicted by multiple examples in the Background section. This includes current knowledge of the underlying disorder and the precise location and mechanism of action of each therapeutic agent.

Once these choices are made, a specific set of agents precisely defines the invention for any particular neurological impairment. This then casts the invention into a set of agents each with unambiguous chemical structures. This defines the invention as to what it is which is driven by what it does.

Examiner has also stated that the terms "impaired" and "deteriorating" in claims 1 and 24 are relative terms which render the claims indefinite. Page 17 of the specification, lines 25 and 26, states that "impaired" neurological function refers to

deteriorating or defective neurological function. The requisite degree, as determined by one skilled in the art (an MD for neurological disorders), refers to any signs or symptoms in a human reflecting any degree of deterioration or defect in neurological function as defined in a well established manner in prior medical art.

The specification on page 1, lines 11 and 12, further states, "deteriorating neurological functions are manifested by a variety of conditions spanning a spectrum of states of nervous system dysfunction". Multiple, non-limiting, examples are listed to help define the broad categories of conditions that are included in the patent. In this context, "deteriorating" or "defective" are synonymous with deficient, faulty, impaired or having fallen to a lower level of quality. Any detectable degree of deterioration falls within the scope of the patent.

For the above reasons, original claims 1 – 52 are believed to be patentable, and their reconsideration and allowance are respectfully requested.

The undersigned attorney requests Examiner Wilson to telephone if a conversation could expedite prosecution. It is believed that no fees are required at this time; however, Applicant authorizes the Commissioner to charge any additionally required fees to deposit account 50-1848.

Respectfully submitted,
PATTON BOGGS LLP

By: _____

Customer Number 024283

Carl A. Forest, Reg. No. 28,494
(303) 379-1114 telephone
(303) 379-1155 fax